UNEP

CBD

CONVENTION ON BIOLOGICAL DIVERSITY

Distr.
GENERAL

UNEP/CBD/ICCP/1/INF/1
23 October 2000

ENGLISH ONLY

INTERGOVERNMENTAL COMMITTEE FOR THE
CARTAGENA PROTOCOL ON BIOSAFETY
First meeting
Montpellier, France, 11-15 December 2000
Item 4.2 of the provisional agenda*

BIOSAFETY CAPACITY-BUILDING: COMPLETED, ONGOING AND PLANNED PROJECTS/PROGRAMMES

Note by the Executive Secretary

1 The Executive Secretary has the honour to circulate herewith, for the information of participants in the first meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP), a summary description of a number of activities related to capacity-building in biosafety undertaken by intergovernmental organizations, regional organizations, bilateral programmes, industry, non-governmental organizations and private foundations. The present submission is intended to supplement the overview of existing and completed capacity-building activities contained in section V of the note by the Executive Secretary on an indicative framework for capacity-building under the Cartagena Protocol on Biosafety that has been prepared for the first meeting of the ICCP (UNEP/CBD/ICCP/1/4).

2. The list of activities does not claim to be all inclusive, but is rather a representative sample of the types of capacity-building projects and programmes being undertaken or planned at all levels. The information provided is derived from that submitted to the Secretariat by various stakeholders as of 15 September 2000, as well as a random survey by the Secretariat of material available on the World Wide Web. Some further details of capacity-building and various technical assistance activities undertaken by countries may be found in the summary of information submitted by Governments on existing national programmes for regulating LMOs and provision of related technical assistance to interested countries contained in annex I to the report of the Executive Secretary on inter-sessional work requested by the Conference of the Parties (UNEP/CBD/ICCP/1/2), which has also been prepared for the first meeting of the ICCP.

* UNEP/CBD/ICCP/1/1.

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INTERNATIONAL ORGANIZATIONS

1. Draft GEF Initial Strategy for Assisting Countries to Prepare for Entry into Force of the Cartagena Protocol on Biosafety

Status/period: Proposed

Location: Global

Lead organization (s): Global Environment Facility

Funding: Global Environment Facility (GEF)

Scope: Biosafety

Objectives: To assist countries to prepare for the entry into force of the Cartagena Protocol on Biosafety through the establishment of national biosafety frameworks, including strengthening capacity for risk assessment and management with a wide degree of stakeholder participation; promote information-sharing and collaboration at the regional and subregional level and among countries that share the same biomes/ecosystems; and promote identification, collaboration and coordination among other bilateral and multilateral organizations to assist capacity-building for the Protocol.

Participating organizations: GEF Implementing Agencies; host Governments in developing countries

Brief description: The activities that are proposed include: assisting interested signatories to the Cartagena Protocol in establishing national biosafety frameworks; individual, country-based demonstration projects, through any of the GEF Implementation Agencies, to assist in capacity-building to implement national biosafety frameworks; coordination with other multilateral and bilateral organizations providing assistance in the area of biosafety; support to enable countries to participate in the Biosafety Clearing-House, once its terms of reference are agreed upon by the Parties; and enhancement of the scientific and technical advice to GEF on biosafety issues.

Preparation of national biosafety frameworks will include: assessment of existing biosafety practices and existing legal instruments or guidelines; identification and involvement of all stakeholders relevant to implementation of the Protocol; identification of actions that need to be undertaken to enable countries to implement the Protocol; preparation of a legal framework and/or guidelines necessary for the implementation of the Protocol, including strengthening capacity for risk assessments and risk management, monitoring and inspection services; establishment of a roster of experts; assessment of options for implementation of various elements of the biosafety frameworks; and an identification of subregional and regional opportunities for harmonizing regulatory frameworks.

Regional and subregional workshops will be convened to promote information exchange and cooperation, with key areas for regional and subregional cooperation including: human resources and expertise; risk assessment, management, monitoring and inspection; review of applications for field trials, field releases, and contained use; and exchange of information.

For support to the implementation of the national biosafety framework, it is proposed that GEF finance a limited number of country-based demonstration projects (two per region for Africa, Asia, Eastern Europe, Latin America and the Caribbean).

Coordination with other multilateral and bilateral organizations will be encouraged, in order to promote greater information exchange on the activities that are being financed, and to support an exchange of lessons learned and an effective and efficient delivery of assistance to developing countries. It is proposed that the GEF secretariat, in cooperation with the Implementing Agencies and the Convention Secretariat, attempt to build synergies and establish complementarity, and share lessons learned.

For support to enable countries to participate in the Biosafety Clearing-House, GEF could be available to provide prompt assistance to the national competent authority to enable participation in the clearing-house. This would require countries to identify a national competent authority responsible for the Biosafety Clearing-House before support could be provided. For the enhancement of scientific and

technical advice to the GEF on biosafety issues, the GEF will solicit the views of experts chosen for their regional diversity and diversity of perspectives on issues relating to the implementation of this strategy. The roster of experts being developed by the CBD Secretariat will be a very useful resource for identifying experts from whom to solicit advice on biosafety issues.

2. UNEP Programme for the Development of National Biosafety Frameworks- Concept for Pipeline Entry

Status/period: Proposed start March 2001

Location: Global

Lead organization (s): United Nation Environment Programme (UNEP)

Funding: Global Environment Facility

Scope: Biosafety

Objectives: The project aims to: strengthen national capacity in order to implement biosafety procedures and maximize the potential of biotechnology; apply biosafety procedures to enhance environmental management; apply biosafety guidelines under the Convention on Biological Diversity and the Intergovernmental Committee for the Cartagena Protocol on Biosafety, taking into account the UNEP International Technical Guidelines for Safety in Biotechnology; harmonize regional and international legal instruments to simplify the process of applying and conforming to regulations; raise public awareness of the issues involved in release of living modified organisms, and their products, to promote informed debate; carry out assessment of technological capacity, its effect on implementation of national biosafety frameworks and means to improve it; and increase the overall safety of biotechnology so those citizens may reap the benefits with minimum adverse effects on health and environment.

Participating organizations: Host government ministries and agencies in developing countries

Brief description: This project is intended to be implemented under the GEF Initial Strategy for biosafety (see item 1 above). The project proposes the following three main activities: preparation of national biosafety frameworks; promoting regional and subregional collaboration on biosafety related issues; and establishment of a global biosafety support programme. Under the first activity — preparation of national biosafety frameworks — there are 100 eligible countries that would be assisted to prepare such frameworks. The national biosafety frameworks will include: national surveys that will provide detailed knowledge of the status of the use of biotechnology and its applications; identification of any existing legal instruments or guidelines that might impact on the use, import or export of living modified organisms; identification of all stakeholders including the private sector and non-governmental organizations in the use of living modified organisms in food and agriculture, and mechanisms for their participation in deciding on the national frameworks; setting up a national roster of experts and a modality for their networking; provisions for subregional/regional consultations for harmonizing guidelines; and drafting of the regulatory frameworks and guidelines, including the implementation of structures required for risk assessment and audit of risk assessments.

The second main activity is the promotion of regional and subregional collaboration on biosafety-related issues. There is a clear need to strengthen regional ties between countries, either by assisting in setting up regional networks or by helping to set up systems with the necessary authorities to oversee the development of biotechnology within the region. Support to regional and subregional cooperation, including through existing regional, subregional, and national institutions and organizations, will facilitate development and the realization of the following key aspects of safety in biotechnology, research, development and application of LMOs/GMOs: human resources and relevant expertise; national and subnational capacities to assess and manage risks associated with products of modern technology; guidelines, methodologies, and procedures for rapid assessment and management of risks and benefits; and networks for supply and exchange of biosafety information.

The main responsibility of the third component — establishment of a biosafety technical support programme — will be to play a proactive role in ensuring that all project national focal points have ready access to appropriate assistance, a dedicated website, and an e-mail list server. The technical programme will also coordinate public awareness-raising activities through the publication of relevant materials and articles.

3. UNITAR Training Programme on Biosafety

Status/period: Ongoing; three-year period from 2000

Location: Geneva and selected developing countries

Lead organization (s): United Nations Institute for Training and Research (UNITAR)

Funding: Being sought from bilateral donors

Scope: Biosafety

Objectives: The main objective of this project is to increase the capacity of a few selected countries in order to establish biosafety legal frameworks and appropriate institutions, in accordance with the requirements of the Cartagena Protocol.

Participating organizations: Proposed involvement of IUCN, UNEP, and the South Center

Brief description: The UNITAR Environmental Law Programme has initiated this project on biosafety capacity-building. UNITAR will implement the project in cooperation with the Secretariat of the Convention on Biodiversity. The programme will increase awareness of biosafety among government officials and stakeholder groups; help them identify priorities and establish appropriate institutions; and support efforts to harmonize legislation in each region. The project will be implemented in two countries each in Africa, Asia, and Latin America. Non-governmental organizations, representatives of consumer organizations and the private sector will be included in the training activities. The process of increasing capacity in the selected countries will consist of a series of workshops, the distribution of materials, the organization of consultation processes, and provision of specific assistance when needed. A series of four training seminars will be an important element of the project addressing: the identification and analysis of the obligations to be fulfilled under the Protocol; the existing legal framework; the legal gaps and needs to implement the Protocol; a workshop on Advanced Informed Agreement procedures; and a workshop on packaging and identification. The project will include the preparation and distribution of materials for a distance learning correspondence course. An important feature of the project will be the selection of regional focal countries for the training activities. To date, Malaysia and the Islamic Republic of Iran have been identified in Asia as focal countries.

4. UNEP/GEF Pilot Biosafety Enabling Activity Project

Status/period: Completed

Location: Regional and country specific: Russia Federation, China, Bolivia, Cameroon, Cuba, Egypt, Hungary, Kenya, Malawi, Mauritania, Mauritius, Namibia, Pakistan, Poland, Tunisia, Uganda, and Zambia.

Lead organization (s): United Nations Environment Programme (UNEP)

Funding: Global Environment Facility

Scope: Biosafety

Objectives: To provide assistance to selected countries in the development of national biosafety frameworks; regional awareness building on risk analysis and management, and on the transboundary movement of living modified organisms.

Participating organizations: Government ministries and agencies in developing countries; other international organizations

Brief description: The project had two components: preparation of national biosafety frameworks in participating countries, including a survey of capacity for both biotechnology and for biosafety; and the organization of a series of eight awareness-raising regional workshops on issues related to biosafety and biotechnology; seventeen countries in the pilot project prepared national biosafety frameworks. The national authority implementing the project in each case identified: the current use of biotechnology; the level of awareness of biosafety; the structures required for risk assessment and audit of these assessments in order to ensure the safe use of biotechnology; and the means by which the safe use of biotechnology could be promoted. A majority of the countries involved in the project have passed or drafted new legislation to control the use of LMOs/GMOs within their borders. The regional workshops were designed to provide a clear understanding and appreciation of biosafety issues including consideration of the UNEP International Technical Guidelines for Biosafety. The workshops addressed risk assessment and management of LMOs concentrating on environmental impacts and the transboundary movement of the organisms, and mechanisms for the supply and exchange of information between importing and exporting nations.

5. Synthesis Report: UNDP/GEF Capacity Development Initiative

Status/period: To be completed 2000

Location: Global

Lead organization (s): United Nations Development Programme (UNDP)

Funding: Global Environment Facility (GEF)

Scope: Multilateral environmental agreements including the Convention on Biological Diversity

Objectives: Assess the capacity development needs of the GEF-eligible countries, including from lessons learned from GEF-financed activities and efforts of other multilateral and bilateral agencies

Brief description: The needs assessment included region-specific and GEF focal-area-specific assessments. For biodiversity, the needs assessment indicates that within the various national frameworks for biodiversity management, Governments face a number of challenges that give rise to a number of needs. Capacity-development efforts need to be aimed at: strengthening the capacity to increase the public awareness of the measures required for the conservation of biological diversity; the mobilizing of existing expertise and the creation of new and improved capacities to ensure effective biodiversity planning; the adoption of appropriate regulatory instruments; and the introduction of appropriate systems, including the development of suitable indicators to monitor biodiversity goals. Similarly, there are a range of institutional, financial and human resources needs for strengthening management capability and improving technical competence in dealing with biodiversity issues. More specifically, capacity-development needs are: development of national legal and regulatory frameworks and policies related to the implementation of the Convention on Biological Diversity; exploitation of synergies between the Conventionon Biological Diversity and the other global conventions; cross-sectoral dialogue and cohesive planning frameworks that eliminate conflicts between policies in different sectors; better linking of biodiversity objectives with social and economic priorities; the involvement in the policy-making process of all stakeholders, including local resource using communities, the private sector, and non-governmental organizations; information and data management; development of incentive systems and methods for economic valuation; participation of the full range of stakeholders, in particular local communities, indigenous groups and non-governmental organizations, in the management of biodiversity; and regional cooperation.

6. UNIDO Biosafety Information Network and Advisory Service (BINAS)

Status/period: Completed

Location: Global

Lead organization (s): United Nations Industrial Development Organization (UNIDO)

Funding: UNIDO, other intergovernmental organizations

Scope: Biosafety

Objectives: Provision of information and technical assistance on biotechnology and risk management; capacity-building for safe use of biotechnology

Participating organizations: International Centre for Genetic Engineering and Biotechnology (ICGEB), UNEP

Brief description: UNIDO is responsible for BINAS (the Biosafety Information Network and Advisory Service), which provides the most comprehensive database of biosafety regulations, and information on field releases of GMOs in developing countries and countries in economic transition. BINAS also provides a monthly news service on developments in biosafety. It contains a number of databases that include biotechnology guidelines, regulations, and standards for the release of transgenic organisms into the environment. UNIDO continues to support a series of awareness-raising seminars and training workshops organized jointly with ICGEB, most of them in close cooperation with UNEP. UNIDO/ICGEB conducts four training courses each year to assist national and regional regulatory authorities and provides ongoing technical support on risk assessment methodologies and biosafety. Training in biotechnology-impact assessment and biosafety has included: Asian Biotechnology and Biosafety-supporting the Farmer-centred Agricultural Resource Management Program (FARM), and "The Significance of Transgenic Plants for Developing Countries" in 1999, which concentrated on plant biosafety and biotechnology assessment and state-of-the-art technology transfer. An earlier biosafety workshop in 1994 focused on creating awareness and strengthening biosafety regulatory frameworks. The workshop involved over 100 biosafety, science and regulatory personnel from Egypt and selected countries from Africa and the Middle East. The workshop addressed policy, risk assessment, and field-testing issues, which surround the management and safe handling of transgenic plants.

7. ICGEBNet and Biosafety Unit

Status/period: Ongoing

Location: Global

Lead organization (s): International Centre for Genetic Engineering and Biotechnology (ICGEB)

Funding: Government of Italy, Government of India; voluntary contributions of participating countries

Scope: Biotechnology and biosafety

Objectives: Training and technology transfer in biotechnology are among the main objectives.

Brief description: ICGEB is dedicated to advanced research and training in molecular biology and biotechnology. It offers services for the dissemination of information on biosafety including annual training courses, free access to a database of scientific studies on biosafety through the ICGEBNet service, and scholarship programmes. ICGEB's Biosafety Unit is available to process requests for information on risk assessment and management of GMOs. There are two main categories of services in the Biosafety Unit: the dissemination of information, and capacity-building. Under the first category, ICGEB maintains biosafety web pages that are dedicated to biosafety and risk assessment and provides all the current available information on biosafety concerns and proceedings world-wide. There are three sites to the web pages: biosafety, the library (a collection of selected documents on biosafety) and the Link (a list of world-wide national agency and international organization websites related to biosafety).

For capacity-building, ICGEB has organized biosafety workshops attended by over 500 scientists from more than 50 countries. Since the last quarter of 1999, ICGEB has collaborated with the Italian Ministry of the Environment in identifying possible cooperative activities for the impact assessment of GMOs, to be implemented by national authorities. ICGEB also offers pre- and post-doctoral fellowship programmes in biotechnology.

8. ISAAA Biosafety Initiatives

Status/period: Completed

Location: Global

Lead organization (s): International Service for the Acquisition of Agri-biotech Applications (ISAAA)

Funding: Foundations in United States and Japan; biotechnology companies in the United States and Europe; Swiss Development and Cooperation (SDC), DANIDA

Scope: Biotechnology and biosafety

Objectives: To support governmental commissions, policy makers, scientists, and special interest groups charged with regulatory oversight for biosafety.

Participating organizations: Rockefeller Foundation, Agway, Monsanto, Centre for Research and Further Studies of the National Polytechnic Institute (Mexico) (CINVESTAV), National Institute for Research in Forestry, Agriculture and Livestock Development (Mexico) (INIFAP), Fox Group, Animal and Plant Health Inspection Service of the United States Department of Agriculture (USDA/APHIS), and the William Brown Fellowship.

Brief description: ISAAA biosafety activities are focused on the establishment of permanent and well prepared national biosafety commissions; the building of a network for facilitating the effective review of field trial applications; enhanced cooperation between countries in the sharing, joint development and adoption of agri-biotechnology applications; increased absorptive capacity of national programmes to acquire, transfer and adopt agri-biotechnology products; increased institutional capacity in biotechnology policy-related aspects; and accelerating the possibility for developing countries to adopt biotech applications with benefits to the environment and a more sustainable agriculture. ISAAA has organized a series of hands-on biosafety training workshops and has developed an internship programme targeted to individuals who are, or will be, on biosafety committees: Central America in 1992 serving Costa Rica and Mexico; South America in 1992 serving Argentina Bolivia, Brazil, Chile, Paraguay; Southeast Asia in 1993 serving China, Indonesia, Malaysia, the Philippines and Thailand; Africa in 1995 focusing on Kenya, Uganda, the United Republic of Tanzania, Zambia and Zimbabwe. ISAAA Biosafety Fellowships for Malaysia, Thailand, Philippines and Brazil have focused on familiarizing individuals with the workings of biosafety regulatory processes.

9. FAO Biotechnology Activities

Status/period: Ongoing

Location: Global

Lead organization (s): Food and Agriculture Organization of the United Nations (FAO)

Funding: FAO, member countries, other international organizations

Scope: Biotechnology including biosafety

Objectives: To support plant biotechnology development and safe use.

Participating organizations: UNIDO, UNDP

Brief description: FAO has developed several instruments that deal with issues pertaining to biosafety including: the International Plant Protection Convention (IPPC); an established "prior informed consent" system; support for building national bio-information systems to assist countries in elaborating pertinent policies and regulations related to biosafety; a draft Code of Conduct on Biotechnology, encompassing a biosafety element; and several biotechnology networks. The networks include the Plant Biotechnology Network (REDBIO); and the Bioinformatics Network on Biotechnology and Biodiversity, in cooperation with UNIDO and UNDP. Jointly with UNDP and UNIDO, FAO launched the Farm-Centred Agricultural Resource Management programme (FARM), which has a subprogramme on biotechnology and biodiversity. FAO also sponsored several workshops on Biosafety and Commercialization of Agri-food Bioproducts in 1998 for Latin American and Caribbean countries. The workshops focused on biosafety, public awareness, and commercialization of biotechnology innovations in plant agriculture.

10. ISNAR Intermediary Biotechnology Service (IBS)

Status/period: Ongoing

Location: Global

Lead organization (s): International Services for National Agricultural Research (ISNAR)

Funding: International organizations

Scope: Biotechnology, including biosafety

Objectives: To support policy and strategy development that enhances capacity in agricultural biotechnology; assist the development of leadership skills among policy makers and research managers for integrating biotechnology into agricultural research programs; and harness internationally available expertise to respond to technical, policy, and management needs.

Brief description: The IBS project began with the purpose of acting as an independent advisor to national agricultural research programmes in developing countries on matters of biotechnology policy and research programme management. A programme of work was developed and funded for the period 1993-1997, with a follow-up phase (1998-2002) approved in 1997. The main activities with particular reference to biosafety included: publishing a research report in 1993 to guide policy makers and research managers in establishing national biosafety systems; detailed analysis of existing biosafety systems; a database on international biotechnology, BioServe; a series of Agricultural Biotechnology Policy Seminars, designed to strengthen the capacity of partner countries in planning and managing agricultural biotechnology; and developing a training course on New Technologies for Agricultural Research: Managing Biotechnology in a Time of Transition. ISNAR has also provided management training programmes in which biosafety plays a prominent role. Sessions cover themes such as: building and implementing biotechnology strategies; managing biodiversity and genetic resources; managing human resources for biotechnology; and managing international technology transfer and intellectual property. Ensuring environmental responsibility and managing biosafety forms a substantial element of the course, in an integrated manner and in close relation to the other course topics such as managing genetic resources.

11. CGIAR Capacity-Building for Biosafety

Status/period: Ongoing

Location: Various regions

Lead organization (s): Consultative Group on International Agricultural Research (CGIAR)

Funding: International organizations, bilateral agencies, and private foundations

Scope: Agricultural biodiversity and biotechnology

Objectives: To strengthen agricultural research capacities, including biotechnology and its safe use.

Participating organizations: See the list under "Brief description" below.

Brief description: A small number of research institutes in the Consultative Group on International Agricultural Research (CGIAR) have focused on working with regulators to establish biosafety regulations for genetically engineered plants, such as the International Centre for Agricultural Research in Dry Areas (ICARDA) working in a number of countries in the Maghreb and the Middle East. They have also provided more general information dissemination and training workshops on policy issues related to biotechnology development and use. There is little evidence of a more concerted effort to develop scientific capacities for risk assessment among the CGIAR family of research institutions. A number of the following CGIAR institutes have been involved in capacity-building for biosafety and in some cases have provided technical assistance to host Governments: International Center for Tropical Agriculture (CIAT); Centre for International Forestry Research (CIFOR); International Maize and Wheat Improvement Center (CIMMYT); International Potato Center (CIP); International Center for Agricultural Research in Dry Areas (ICARDA); International Centre for Living Aquatic Resources Management (ICLARM); International Centre for Research in Agroforestry (ICRAF); International Crops Research Institute for the Semi-Arid Tropics (ICRISAT); International Food Policy Research Institute (IFPRI); International Institute of Tropical Agriculture (IITA); International Livestock Research Institute (ILRI); International Plant Genetic Resources Institute (IPGRI); International Service for National Agricultural Research (ISNAR); International Water Management Institute (IWMI); and West Africa Rice Development Association (WARDA).

12. ILO Study on the Impacts of Modern Technology

Status/period: Completed

Location: Geneva

Lead organization (s): International Labour Organization (ILO)

Funding: ILO members

Scope: Biotechnology, including biosafety

Objectives: To address biotechnology safety and risk assessment and management issues in the workplace.

Brief description: In 1993, the International Labour Conference adopted a resolution concerning exposure to and safety in the use of biological agents in the workplace. The governing body of the ILO requested that the Director-General take fully into account in the ILO programme the question of exposure to and safety in the use of biological agents at work; and consideration of the need for international instruments in order to minimize the risks to workers, the public and the environment. ILO has prepared a study on the impact of modern technology, including gene technology, on workers' health and the environment. The study identifies potential risks related to the introduction of these new technologies.

13. UNCTAD/UNEP Capacity-Building Task Force on Trade, Environment and Development

Status/period: Ongoing

Location: Geneva

Lead organization (s): United Nations Conference on Trade and the Environment (UNCTAD) and UNEP

Funding: UNCTAD, UNEP, bilateral agencies

Scope: Trade and environmental linkages including biotechnology and biodiversity.

Objectives: To strengthen the capacities of countries, particularly developing countries and countries with economies in transition, to effectively address trade-environment-development issues.

Brief description: Through the UNCTAD Division on International Trade in Goods and Services, and Commodities, the following activities are being carried out: capacity building and policy analysis in the field of biodiversity and biotechnology in collaboration with UNEP; advice on policy and capacity-building, at the request of governments, on issues related to genetically modified organisms; and the BIOTRADE initiative which aims at stimulating investment and trade in biodiversity products and services.

14. European Commission International Cooperative Programme (INCO)

Status/period: 1995-present

Location: Developing countries in Asia, the Pacific, Latin America and Caribbean , Africa

Lead organization (s): European Commission

Funding: European Commission

Scope: Biotechnology including biosafety

Objectives: To support the sound management and use of biotechnology

Brief description: The main activity areas relevant to biosafety under the INCO programme are: the promotion of enabling mechanisms and capacity-building to support countries in developing risk assessment and management and broader biotechnology-oversight mechanisms; and joint regional activities with developing countries, concentrating on biotechnology applications for agriculture, health and natural resources management. From 1995 to 1998, over 126 projects and activities related to biotechnology were financed by the European Union and carried out in cooperation with developing countries. This collaboration encompasses joint research projects, the organization of workshops for exchange of information on technical issues and policy matters, including regulations and product authorization procedures for GMOs. Approximately 200 post-doctoral fellowships in biotechnology for researchers from developing countries have been supported. Capacity-building specifically targeted to biosafety includes funding for genetic resources and biosafety projects in Asia, Latin America, and Mediterranean countries and development of methodologies to assess and conserve biodiversity.

BILATERAL AGENCIES AND PROGRAMMES

15. German Biosafety Capacity-Building Initiative for the Implementation of the Cartagena Protocol

Status/period: Ongoing

Location: Location to be determined according to demand

Lead organization (s): German Federal Ministry for Economic Cooperation and Development (BMZ)

Funding: BMZ

Scope: Biosafety

Objectives: To assist countries in elaborating and implementing biosafety frameworks and to provide tools for training.

Brief description: This project, launched in 1999, includes demand-driven activities that will depend on the country's needs. The main elements are: assistance in the formulation of biosafety legislation and implementation of existing or new regulations; institutional capacity-building; public-awareness building; and risk assessment. Activities involve policy makers, government, industry, representatives of non-governmental organizations, scientists, trainers, and teachers. The project intends to assist in defining the

state-of-the-art within a given country; to suggest a participatory mechanism for the formulation of biosafety policy; to comment on the minimum requirements of a legal and administrative infrastructure; to provide advice and scientific knowledge on the development of risk assessment procedures, based on the precautionary principle; to enable and facilitate decision-making; to determine benefits, objectives, and limitations of monitoring procedures; and to formulate evaluation criteria for assessment of biosafety policy. The initiative includes the development of a Biosafety Capacity Building Instrument which, in its first phase, consists of: a document providing orientation; background information and explanations on suggested training exercises; a set of transparencies and training modules; an off-line library; a database providing a "biosafety-profile" of Members of the United Nations; a list of relevant electronic publications; and case-studies.

16. Netherlands Implementation of National Biosafety Frameworks in Pre-Accession Countries of Central and Eastern Europe

Status/period: 1999-2002

Location: Participating countries in Central Europe

Lead organization (s): Netherlands Ministry of the Environment

Funding: Netherlands Ministry of Foreign Affairs

Scope: Biosafety

Objectives: Support pre-accession countries in Central and Eastern Europe in establishing adequate, workable, and transparent national biosafety frameworks, in conformity with relevant European Community directives and other international obligations.

Participating organizations: UNEP Regional Office for Europe, the Baltic Environmental Forum, the Regional Environmental Centre, and agencies in participating countries.

Brief description: The project aims at assisting the participating countries in establishing or strengthening a regulatory framework for biosafety, and a system for implementation of the regulatory framework, mechanisms for risk assessment and risk management, and approaches for the provision of public information. The initial phase of the project involved obtaining a state of development of the biosafety framework, and drafting an outline for specific training in each participating country. Introductory seminars were organized to reach this goal. All participating countries requested immediate assistance in reviewing existing and/or draft legislation. Outreach activities included collaboration with experts from other countries and organizations; strengthening or initiating regional activities; and creating arrangements to allow observers from other countries to participate. Following the initial assessment of the project, further activities will include: two training courses on contained use regulations, and on handling requests for release of GMOs. Work will also continue to provide technical assistance to Central and Eastern European countries through expertise made available by other European Union countries; and further regional activities including meetings on biosafety, a regional website, and establishment of subregional support centres, including in the Balkans.

17. Danish Assistance to Capacity-Building in Biosafety

Status/period: Ongoing

Location: Regional; Estonia, Latvia, and Lithuania; Thailand

Lead organization (s): Danish Cooperation for Environment in Eastern Europe (DANCEE) and Danish Corporation for Environment in Developing Countries (DANCED)

Funding: DANCEE, DANCED

Scope: Biosafety

Objectives: To help build capacities to manage risk assessment requirements for LMOs

Brief description: DANCEE is currently preparing a workshop in Denmark for the three Baltic countries Estonia, Latvia and Lithuania, concentrating on the practicalities of managing the requirements to administering the European Union directives on GMOs, with regard to risk assessment. The officials dealing directly with the administration in the relevant ministries and departments in the three countries will be invited to participate. The Danish expertise will be drawn from ministerial departments and research institutions as well as those people handling the applications for use of GMOs. In addition, DANCEE is sponsoring a preparation of a practical information guide to the Cartagena Protocol directed at its cooperation partners in Eastern Europe and the Russian Federation.

In a separate Danish project, DANCED is supporting a study tour for experts from Thailand in administration and research in GMO/LMO agricultural products. Further possibilities for cooperation between Danish and Thai experts will be pursued, in particular in relation to the implementation of the Cartagena Protocol.

18. International Workshop on Biosafety Regulatory Capacity-Building (Canada-Mexico Workshop)

Status/period: Completed

Location: Mexico/global scope

Lead organization (s): Canadian Department of Environment; Mexican Ministry of Environment, Natural Resources and Fisheres

Funding: Government of Canada, Government of Mexico

Scope: Biosafety

Objectives: To provide an opportunity to explore further practical efforts in biosafety regulatory capacity building to meet the emerging needs of developing countries and countries with economies in transition to implement the Biosafety Protocol.

Brief description: The Workshop examined the basic elements of biosafety regulatory frameworks, explored the experience gained in countries with economies at different stages of development in implementing a biosafety framework and reviewed current capacity-building initiatives. Special emphasis was placed on identifying the emerging needs of developing countries and countries with economies in transition to implement the basic elements of a biosafety regulatory system as envisaged by the Biosafety Protocol. Papers on the experience to date were presented by Canada, the United States, the United Kingdom, Mexico and the Russia Federation. Cameroon, India, Malaysia, and Brazil presented papers on their emerging needs to manage biosafety. Papers by UNEP, ISNAR, the European Commission, Australia, Canada, the United States, and Japan described and assessed current capacity-building efforts. Participants discussed four topics in workshops, each of which produced a summary report of discussions: regulation; risk assessment and risk management; administrative implementation; and information supply and public participation. These workshops are described below.

Workshop 1: Emerging needs in regulation: different ways of implementing biosafety regulations

The workshop focus included biosafety regulations on LMO-related development activities that range from regulations on contained uses to confined releases, small- and large- scale field trials, deliberate field releases, and the consumption of products, including transboundary movement, in order to safeguard the biologically diverse resources and the environment as well as human and animal health. Emerging needs for biosafety regulation in developing countries and countries with economies in transition depend largely on the existing level and anticipation of the development of modern biotechnology within respective countries and/or regions. Of immediate concern are the regulations on notification and applications for importation for contained use and field trials of transgenic plants or animals from developed countries to be carried out in countries with no biosafety regulation or guidelines available or

being enforced. In addition to the lack of appropriate biosafety regulation, these countries also lack required human resources and experience to handle such tasks and responsibility.

Workshop 2: Risk assessment and risk management

The workshop identified risk assessment needs including:

(a) Identification of necessary experience and training for risk assessment using the following strategies: use of the UNEP Guidelines as starting points to identify disciplines; having flexibility to bring in other disciplines as necessary; identifying personnel to be trained- a core group who can then train others to maximize continuity; provision of hands on training through an iterative process which builds on existing efforts; and using existing regional efforts as models for other regions;

(b) Identification of information that is needed – e.g., on biodiversity, on local crops, on centres of origin and diversity, using the following strategies: regional efforts on centres of origin; and collection of information on crops used at local or regional level;

(c) Identification of information that is available and systems for accessing the information in real time, using the following strategies: compilation of websites; provision of Internet access points that can then disseminate information to the rest of country; mailings of risk assessment reviews; and establishing closer links between government, private, and research institutes;

(d) Access to experts through rosters at the regional and international levels.

Risk management and risk mitigation needs include:

(a) Appropriate facilities and technical resources, to be addressed through centres of excellence on a regional basis;

(b) Human-resource training through: hands-on training, remembering that those to be trained may differ from those people involved in risk assessment; and use of regional institutions to help with national programmes;

(c) Sharing of experiences through workshops at regular time frames at the regional and international levels, and the provision of internships;

(d) Risk management communication through effective use of media, public information meetings, and use of industry to communicate risk management to users.

Workshop 3: Administrative aspects of implementing biosafety regulations

The lack of experts in the field was identified as a key constraint. This is reflected by the general insufficiency of knowledge of the subject matter, as well as by the gaps in specific areas of biosafety in the different countries. These deficiencies can be observed both at the level of the competent authorities and at the level of the advisory bodies. A number of approaches were proposed to address these, including a national-level mentoring programme, in addition to educating and training people within the country. At the regional level, it was proposed to create regional groups of experts in order to fulfil the needs for expertise in subjects important in the different geographic regions. At the global level. the workshop agreed that a possible solution might consist of putting a list of independent experts at the disposal of the countries, to be included in the mechanism already in place for the exchange of information under the Convention on Biological Diversity. With regard to handling of notifications, the workshop identified the lack of human resources as one of the principal areas that must be addressed.

Workshop 4: Information supply and public participation

Discussions were broad in scope and emphasized the importance of education and dissemination regarding biotechnology and biodiversity more than information supply and public participation in the decision-making processes regarding biosafety. Public acceptability of regulations and decision making in biosafety is a very important issue related to all aspects of information supply and public participation (education, dissemination, the Biosafety Clearing-House, etc). In particular, it is important to produce information related to risk assessment and management regarding specific releases of LMOs to the

environment. An important issue that was raised is the need to build the capacity of government officials to assess information contained in the advanced informed agreement notification and in the risk assessment, in order for them to make it available to the public. A simple disaggregation of the public clearly reveals the need to develop specific materials for target audiences.

19. Canada-Latin America Initiative on Biotechnology for Sustainable Development (CamBioTec)

Status/period: Ongoing

Location: Latin America

Lead organization (s): BIOTECanada, in collaboration with International Development Research Centre (IDRC) and Canadian International Development Agency (CIDA)

Funding: IDRC and CIDA; to be self-financing by the end of 2000.

Scope: Biotechnology, including biosafety

Objectives: To foster commercialization of modern technologies in Latin America, specifically to help set national research and development priorities in biotechnology; strengthen public policies in biotechnology; strengthen the management of innovation in research and industry; and foster strategic alliances.

Participating organizations: Canadian government ministries and Canadian biotechnology firms

Brief description: CamBioTec is a collaboration between the biotechnology industry and government ministries in Canada and certain Latin American countries, with financial support from development cooperation agencies. CamBioTec's main capacity-building activities relate to the promotion and adoption of biotechnology, and include biosafety regulation of agri-food biotechnology products. The CamBioTec capacity-building programme in biosafety and public awareness for agri-food biotechnology products was entitled "Biotechnology Development in the Southern Cone". It was developed in response to the needs of local biosafety regulatory agencies and bioindustry community in these countries, and involved three capacity-building areas: biosafety information systems, biosafety regulatory systems including development of risk assessment and managements skills; and public awareness of the benefits and risks of agri-food biotechnology products. This project element has involved the participation of national regulatory agencies from Canada, Argentina, and Chile. Other activities under the initiative have included a biotechnology/biodiversity workshop; a seminar on harmonization of biosafety regulations; and a seminar on biosafety in agricultural and agri-food biotechnology.

20. Indo-Swiss Collaboration in Biotechnology (ISCB)

Status/period: Ongoing

Location: India

Lead organization (s): Swiss Development and Cooperation (SDC) and Government of India

Funding: SDC

Scope: Biotechnology

Objectives: To build biotechnology research and development capacity for commercial product development.

Participating organizations: Indian Institute of Technology; Swiss Federal Institute of Technology

Brief description: The programme was established to explore ways of cooperating in various areas related to biotechnology. The core of the collaboration was capacity-building for biotechnology research and development in phase 1 (1974 – 1998). In phase 2, it is centred on the development of biotechnology

products and processes. Phase 1 capacity-building was initially focused on curriculum, infrastructure and human-resources development in biochemical engineering. Capacity-building activities have been carried out alongside research activities, including short- and long-term training to strengthen knowledge and skills in newly emerging technologies among researchers from public, private and government institutions; purchase of laboratory and other research tools; and provision of technical assistance on biosafety issues related to research activities. Phase 2 efforts are being broadened beyond research collaboration to include potential future users of biotechnology such as small-scale farmers, industrial producers, regulating state agencies, other authorities dealing with biosafety matters, and organizations dealing with ethical issues.

21. United States Agricultural Biotechnology for Sustainable Development Project (ABSD)

Status/period: Ongoing

Location: Various countries in Asia, Africa and Latin America

Lead organization (s): United States Agency for International Development (USAID)

Funding: USAID

Scope: Biotechnology including biosafety; biodiversity

Objectives: To improve the capacity and policy environment for the use, management and commercialization of agricultural biotechnology in developing countries and transition economies

Participating organizations: United States federal agencies, United States universities, agencies and institutions in participating countries

Brief description: The ABSD project takes an integrated approach, combining applied research, product development, and policy development — the latter primarily related to biosafety and intellectual property rights (IPR) — to help developing countries use and manage biotechnology. ABSD works with United States agencies such as the Department of Agriculture, providing workshops and internships to facilitate the advancement of human resources in developing countries. It also provides collaborators in participating countries with advice on scientific, technical and regulatory issues related to exportation, importation, and safe handling of GMOs. To further strengthen the biosafety regulatory framework in Latin America and the Middle East, ABSD has organized two regional biosafety workshops. The workshops for Latin America were carried out in 1993 and were co-sponsored by the Bean Cowpea Collaborative Research Support Programme, and the Jamaica Agricultural Research Programme. They focused on examining the status of biosafety guidelines and regulations in the region for testing and utilization of genetically engineered food crops, and on assisting participants in developing work plans and recommendations from which to begin building the necessary biosafety policies and guidelines in their respective countries.

REGIONAL ORGANIZATIONS

22. African Agency of Biotechnology (AAB) Plant Biotechnology Programme

Status/period: Ongoing

Location: Regional: Africa:

Lead organization (s): African Agency of Biotechnology

Funding: Voluntary contributions paid by member States

Scope: Biotechnology including biosafety

Objectives: To promote a strategy for the development of modern and traditional biotechnologies to efficiently resolve the problems of development, the preservation of the environment, as well as the quality of life in Africa.

Participating organizations: Government ministries responsible for plant in biotechnology: Algeria, Burkina-Faso, Burundi, Cameroon, Cote d'Ivoire, Egypt, Ethiopia, Gabon, Ghana, Mauritius, Kenya, Morocco, Nigeria, Senegal, Tunisia, Zimbabwe

Brief description: The AAB programme focuses on several priorities, including: plant biotechnology; human and animal health; animal production; protection and conservation of nature; industrial production; and biodiversity-biosafety-bioethics. Its work includes the reinforcement of national capabilities of the member States in biotechnology, especially in terms of training, research, equipment, and infrastructures; the coordination and promotion of cooperative programmes in areas of priority biotechnological applications for the development of the member states; the encouragement of the production, distribution and commercialization of biotechnological products in relation to the objectives of sustainable development and the necessity of preserving the environment; and development and harmonization of regulations pertaining to biosafety, bioethics, intellectual property rights, patent rights.

23. APEC/ATC Workshops on Biosafety Regulation

Status/period: Completed

Location: Regional, Canberra (1997), Honolulu (1998), and Kuala Lumpur (1998)

Lead organization (s): Asia Pacific Economic Cooperation/ Agricultural Technical Cooperation Experts' Group (APEC/ATC)

Funding: Member countries

Scope: biosafety

Objectives: To promote harmonization of biosafety regulatory requirements in the developed and developing country members of APEC.

Participating organizations: Government ministries in participating countries

Brief description: The APEC/ATC Group held a number of workshops to address the imbalance between member economies in biosafety regulation. These covered biosafety, risk assessment, information exchange, research and regulation, and capacity-building for risk assessment and risk management.

24. ASEAN Seminar on risk assessment and public awareness of agricultural products derived from biotechnology

Status/period: Completed

Lead organization (s): Canadian and United States government agencies, National Science and Technology Board of Singapore

Funding: Association of South East Asian Nations (ASEAN)

Scope: Biosafety

Objectives: To promote harmonization of regulations for agricultural biotechnology in ASEAN countries.

Participating organizations: Government ministries responsible for agricultural biotechnology in ASEAN member countries.

Brief description: The seminar focused on providing ASEAN member countries with an opportunity to better understand how to carry out risk assessment for agricultural products derived from biotechnology. It was offered in conjunction with a program to harmonize ASEAN biotechnology regulations within two years, under the ASEAN Task Force on the Harmonization of Regulations for Agricultural Products derived from Biotechnology.

INDUSTRY

25. BIOTECanada Training in Biosafety

Status/period: 1997 –1999; and ongoing

Location: Latin America

Lead organization (s): BIOTECanada

Funding: International Development Research Agency, Pan-American Health Organization

Scope: Biosafety

Objectives: Training of regulatory officials and researchers on guidelines, policies and strategies for biosafety risk assessment and management

Participating organizations: Government agencies in Mexico, Chile, Argentina; Canadian government departments; United States government departments

Brief description: A series of training workshops and seminars were carried out in selected Latin American countries. The Seminar on Harmonization of Biosafety Regulations focused on training of Mexican regulatory officials and researchers on the need to harmonize biosafety regulations *vis-à-vis* the North American Free Trade Agreement. The Workshop on Biosafety in Agricultural and Agri-Food Biotechnology focused on training Argentinian regulatory officials and researchers on risk assessment and information sharing. The Workshop on Introduction to Risk Assessment and Management: Elements for Setting Policies in Environmental Health focused on discussion of guidelines for establishing suitable policies and strategies in the risk assessment and management process.

26. Europabio – Capacity-Building Framework

Status/period: Ongoing

Location: Europe

Lead organization (s): European Association for Bioindustries (Europabio)

Funding: Industry association

Scope: Biotechnology and biosafety

Objectives: To be a promoting force for biotechnology.

Brief description: Europabio is involved in the research, development, testing, manufacturing, sales, and distribution of biotechnology products and services in the fields of healthcare, agriculture, food and the environment. One of Europabio's objectives is to encourage through dialogue and consensus better mutual understanding of ethical concerns related to biotechnology. Europabio has prepared a framework for capacity building requirements for biosafety in developing countries, which identifies key needs for regulation of health and safety of humans and environmental safety.

27. Japan Bioindustry Association – Bilateral Cooperation On Conservation and Sustainable Use of Tropical Bioresources

Status/period: 1993–1999

Location: Indonesia, Malaysia, Thailand

Lead organization (s): Japan Bioindustry Association

Funding: Japanese New Energy and Industry Technology Development Organization (NEDO)

Scope: Biotechnology and biodiversity

Objectives: To promote information-sharing between biotechnology industry and government agencies responsible for biotechnology research and development.

Participating organizations: Agency for the Assessment and Application of Technology (Indonesia); National Biotechnology Directorate (Malaysia); National Science and Technology Development Agency (Thailand)

Brief description: The project focused on research and development, as well as human resource development, for the conservation and sustainable use of tropical bio-resources. The Japan Bioindustry Association implemented the project on behalf of NEDO. A separate initiative by a number of Japanese biotechnology companies was group training in bioindustries, which focused on human resources training and sharing of expertise in a range of skill areas relevant to biotechnology, and on conservation and sustainable use of natural resources.

28. Capacity-Building Efforts of Individual Biotechnology Companies

Status/period: Proposed, ongoing and completed

Location: worldwide

Lead organization (s): A large number of companies including Agribiotechnologia de Costa Rica, AgrEvo GmbH, ANPROS (Chile), Asgrow Seed, Cargill, Dupont, ELM/Seminis, ICI, Monsanto, Mitsubishi Chemicals, Novartis, Pioneer Hi-Bred International, ProAgro (India), Schering, Zeneca Plant Sciences

Funding: Individual companies, often in cooperation with one or more of developed country bilateral development cooperation agencies and national ministries responsible for biotechnology; international research organizations; private foundations

Scope: Biotechnology including biosafety, benefit-sharing

Objectives: To develop awareness and capacities for biosafety in support of research, development, transfer and use of biotechnologies in developing countries and countries with economies in transition.

Participating organizations: Developing country research institutions, regulatory officials, biotechnology industry, OECD country universities

Brief description: An example is the Novartis biosafety programme, which has as its purpose to minimize the potential hazards in the handling of biological materials. The company has worked with research institutions in such countries as Indonesia, Philippines, Thailand and Viet Nam to develop their capacities in biotechnology, including specifically on regulatory aspects of field trials, product development and distribution. It is planning to fund a pilot biosafety programme for a selected country in Africa, to be used as a model for other countries. An other example is Monsanto, which is working with selected research institutions in developing countries to develop biotechnology research capacity related to specific types of LMO products, with companion capacity-building activities in risk assessment and LMO regulation. This has involved work in Kenya, Mexico, Indonesia, Philippines, Thailand, Malaysia and Viet Nam.

NON-GOVERNMENTAL ORGANIZATIONS

29. TWN Briefing Sessions, Publications on Issues Related to Genetic Engineering

Status/period: Completed

Location: Global

Lead organization (s): Third World Network (TWN)

Funding: Various sources

Scope: Biosafety

Objectives: Stakeholder and public-awareness building.

Participating organizations: Greenpeace, the Edmonds Institute

Brief description: The Third World Network has been active in undertaking briefing sessions on LMOs, providing scientific documentation, and producing a series of papers on various aspects of LMO development and use. Briefing sessions have involved experts addressing key scientific and legal issues related to genetic engineering. Papers have included those on socio-economic aspects of LMOs, ethical issues and biosafety law and regulation.

30. The Edmonds Institute — Assessing Ecological and Human Health Effects of Genetically Engineered Organisms

Status/period: Ongoing

Location: Global

Lead organization (s): The Edmonds Institute

Scope: Biosafety

Objectives: To build public awareness, and promote education and information sharing about the environment, biotechnology and intellectual property rights.

Brief description: The Edmonds Institute has organized workshops and lectures on biosafety and the social and ethical impacts of new technologies. These have been given to various audiences in the United Kingdom, the United States, Spain, India, Denmark, Switzerland, Denmark, Colombia, and Indonesia. It has produced a Manual for Assessing Ecological and Human Health Effects of Genetically Engineered Organisms, which is a biosafety handbook accessible to the public and reflective of concerns for ecological and human health.

PRIVATE FOUNDATIONS

31. Rockefeller Foundation Research Capacity-Building on Agricultural Biotechnology

Status/period: Ongoing

Location: Selected countries in Asia, Africa, Latin America

Lead organization (s): Rockefeller Foundation

Funding: Foundation resources

Scope: Agricultural biotechnology for food security, and biosafety

Objectives: To develop plant biotechnology research and development capacities in developing countries, including biosafety procedures.

Participating organizations: A wide range of developing country research institutions, CGIAR-system international research institutions, international organizations, developed country government agencies, individual companies

Brief description: The Foundation is active in developing research and development capacities in developing countries including biotechnology such as for drought-resistant seeds. As an example of its capacity-building work, the Foundation has supported development of virus resistance in potatoes since 1991. A companion project is assisting Mexico in developing the infrastructure and biosafety regulatory procedures for testing and introducing recombinant products. In collaboration with Novartis, the Rockefeller Foundation supported the ISAAA biosafety workshop in Costa Rica in 1992. The workshop focused on the development of capacity for regulating field trials of transgenic crops. In April 1994, together with United States government agencies, it funded an ISAAA biosafety workshop, in Indonesia. The workshop focused on the development of capacity for regulating field trials of transgenic crops and exploring the possibility of regionalizing regulations and harmonizing approaches. Participating developing countries included China, Indonesia, Malaysia, Philippines, Taiwan, Thailand, and Vietnam. In 1998 it supported another ISAAA biosafety workshop focused on the development of harmonized field trial application of transgenic papayas.

32. Swaminathan Foundation Asia-Pacific Workshop on Biosafety: Environmental Impact Analysis of Transgenic Plants

Status/period: Completed

Location: India, Asia Regional

Lead organization (s): M.S. Swaminathan Research Foundation

Funding: Various sources

Scope: Agricultural biotechnology and environmental biosafety

Objectives: To support research and community action to harness science and technology for environmentally sustainable and socially responsible equitable development in the fields of agriculture and rural development.

Brief description: The Swaminathan Research Foundation's programme on biodiversity and biotechnology focuses on the development and sustainable management of community agriculture. The Foundation has been involved in biotechnology and biosafety training, including organizing an Asia-Pacific Workshop on Biosafety in 1997, which focused on environmental impact analysis of transgenic crops.
